DSJ1&2-PR Exh 555

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Suspicious Order Monitoring Project Status Review

Morristown, NJ

November 8, 2011

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Project Team

Actavis Inc.

Project Sponsors	Michael Perfetto - VP, Sales & Marketing Bill Ostrowski - Sr. Director IT
Project Team	Nancy Baran - Director, Customer Service Umesh Solanki - IT Manager Wonson Park - IT Consultant Tracey Van Dillen - Legal Litigation Counsel
Tactical Team	Ara Aprahamian - Director, Pricing & Contracts Jinping McCormick - Director Marketing Mike DiBlasi - Senior Director, Supply Chain

Cegedim Compliance Solutions

Consultant Support	Robert C. Williamson - Manager, DEA Consulting Jonathan Kuhn, PhD. Statistician

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Suspicious Order Monitoring Requirement

Controlled Substances – Requirement 21 CFR 1301.74 (b)

- The registrant shall design and operate a system to disclose to the registrant suspicious orders of controlled substances. The registrant shall inform the Field Division Office of the Administration in his area of suspicious orders when discovered by the registrant.

Suspicious orders include:

- Orders of unusual **size**
- Orders deviating substantially from a **normal pattern**
- Orders of unusual **frequency**

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SOM Related Penalties / Actions

- A growing number of companies have had actions taken against them by DEA for having non-compliant SOM programs and inadequate "know your customer" approaches.
- DEA Actions related to SOM / "know your customer" since 2007
  - Immediate suspension/loss of DEA registrations
  - Criminal prosecution
  - Substantial Civil **Fines exceeding $132 M**
    - CVS, Cardinal, McKesson & Harvard Drug
- Registrants' SOM approaches have been a focus during DEA "Distributor Briefings"
  - At the 19th National Conference On Pharmaceutical and Chemical Diversion (June 2010), DEA reiterated their intention to "meet with each and every registered Distributor and Manufacturer to discuss their due diligence responsibilities found in Title 21 CFR Part 1301.74 (b)"

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SOM PITFALLS

System Challenges & Responses

- "Threshold" based systems are not sufficient
- "Cutting" orders to a volume that puts the order under a threshold is not acceptable.
- DEA has stated on this topic, "That is like saying a little bit of diversion is okay."

Investigative Challenges & Responses

- Potentially suspicious orders must be reviewed before shipment occurs. Investigation must be fully documented.
- Well defined and sufficient "due diligence"
  - Confirm the legitimacy of new (and existing) customers.
  - **Balance:** Motivation to quickly clear legitimate orders vs. regulatory need to hold/cancel/report on orders that are truly "suspicious"
  - Reporting on orders as suspicious will not absolve the registrant of responsibility if the registrant knew, or should have known, that the controlled substances were being diverted.

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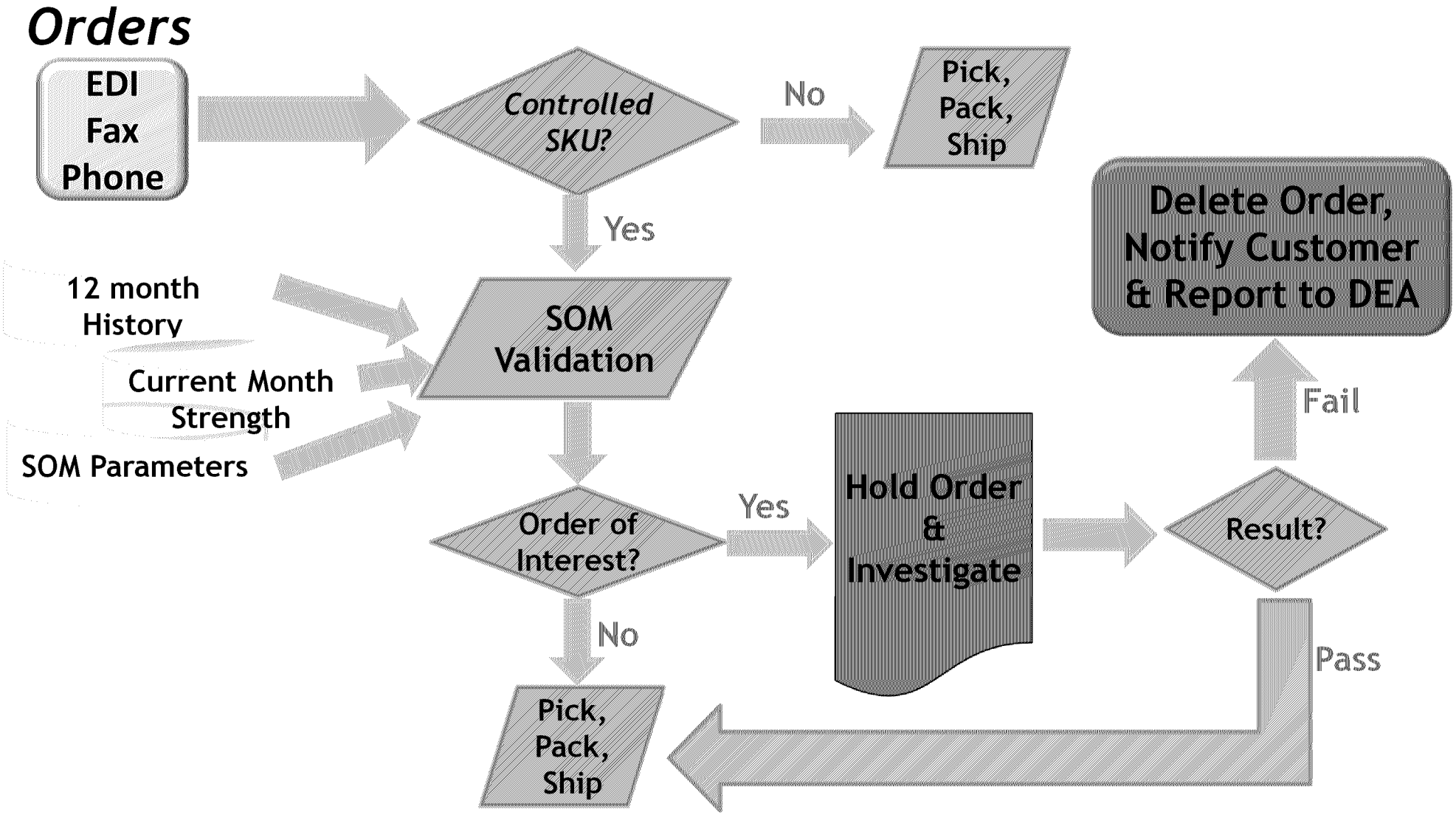
SOM RECOMMENDATIONS/APPROACH

1. Engaged Cegedim Compliance Solutions (formerly Dendrite) Summer 2011
2. Enhance SOM systems: Develop a new SOM statistical model using Ph.D. statisticians and DEA consulting team.
   - Implement into existing order management system
   - Extensive data review and analysis model developed based on this.
3. SOM model maintenance support
   - Model was developed using historical data as a start (rolling 12-months)
   - Model coefficients are fixed – relating back to original data provided
   - Model fully retuned yearly based on a more current sample of data
4. Develop SOP's, Processes, Best Practices
5. Site Visits- Know your customer

SOM - Proposed Solution



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Project Status

- Model/Prototype has been developed within our Systems - *Complete*
- Model is currently being fine tuned and validated- *In Progress*
- Inform Key Stakeholders of Project Status: *ET - Nov. 8 & Site Leaders Mid-Nov.*
- Preparation and Execution of Test Scripts - *target end of November*
- Assign key process owners, Develop Cross-Functional Team - *target Dec 1*
- System documentation sign-off and implementation -*target mid-December*
- Rough draft SOP's complete. *target mid- December*
- Enhanced SOM Systems and Processes - *ready for Go-Live - end of Dec. Parallel - January 9 (low impact) with February 1 (full impact)*

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"Know your customer's Customer" initiative

- SOM Process Review with Customers beginning with key accounts

  Completed: Cardinal, ABC, McKesson

  Scheduled: HDSmith *(week of 11/14)*, Nucare *(to be scheduled)*

- *Cardinal –* *VP, Supply Chain Integrity & Senior Regulatory Counsel*
  Quality & Regulatory
- *ABC –* *VP, Corporate Security & Sr. Director Regulatory Counsel*
  Regulatory Affairs
- *McKesson -* *Senior Manager, Supply Chain Services*
  Supply Chain
- *HDSmith –* *Director, Compliance & Security*

- Customer Site Visits during 2012 – more in-depth review of SOM Processes
- Develop Systems & Processes to manage Indirect Sales

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Accountability - Cross-Functional Team

- ❑ Manage Overall Compliance
- ❑ DEA Surveillance/Intelligence
- ❑ New Customer Review/Approval Process
- ❑ Manage 3PL SOM Process
- ❑ *Manage Actavis Direct Sales - SOM Process*
- ❑ Manage Existing Business: Total Sales as a % of Controls vs. Non-Controls
- ❑ Manage certain controlled drugs - Sales by State
- ❑ *Manage Indirect customer sales data*
- ❑ Customer Site Visits
- ❑ Lead DEA Audits
- ❑ Retune SOM Model - yearly basis